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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,817	01/07/2005	Henrik Lindenskov Nielsen	P70346US0	5100

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JACOBSON HOLMAN PLLC
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WASHINGTON, DC 20004

EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/520,817	Applicant(s) NIELSEN ET AL.	
	Examiner Michael G. Bogart	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01 June 2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

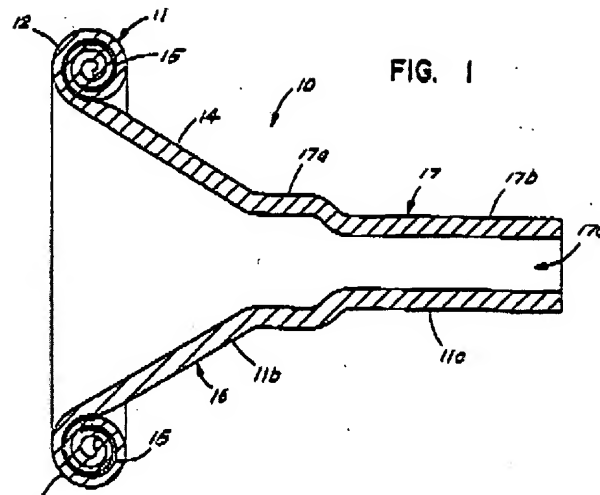
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. § 102(b) as being anticipated by Conway (US 5,376,085 A; hereinafter: “Conway”).

Conway teaches an external urinary catheter (10), comprising a tip portion (16) and a sheath portion (11), said external urinary catheter (10) having at least one area of the external urinary catheter is transparent and/or permeable (col. 5, lines 27-38)(see figure 1, *infra*).

The limitation “manufactured by thermoplastic processing” is a product-by-process limitation. Product-by-process limitations are limited to the recited steps, only the structure implied by those steps. MPEP § 2113. Silicone rubber is a thermoplastic as it is capable of softening or fusing when heated and of hardening again when cooled.



Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

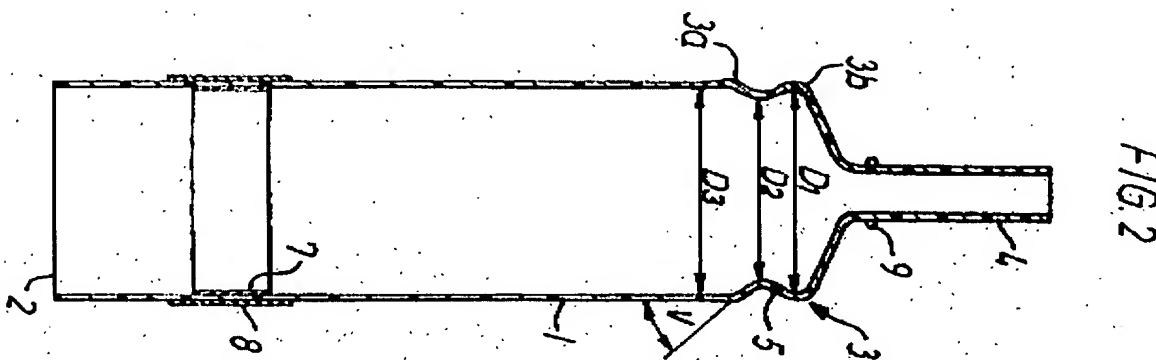
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 23-27 and 44, 45 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wendler (US 5,554,141 A) in view of Oda *et al.* (EP 1 062 957 A1; hereinafter: "Oda").

Wendler teaches an external urinary catheter (1) and method of making the same, comprising a tip portion (34) and a sheath portion (1), said external urinary catheter (1) having thermoplastic construction (abstract)(col. 5, lines 27-38).



Wendler is silent as to the catheter's transparency.

Oda teaches a flexible, elastic and transparent medical device including a catheter comprising a composition of styrene-ethylene random copolymer and a plasticizer to which further polymeric compounds can be added (paragraphs 0001, 0002, 0008, 0009 and 0065, and 0076).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the transparent materials of Oda in the condom catheter of Wendler in order to make it transparent as is required for some medical devices so a caretaker/wearer can see its contents (see Wendler, paragraph 0003).

Regarding claim 26, Wendler teaches a slip additive (col. 6, lines 35-46).

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Regarding claim 27, one of ordinary skill in the art would have recognized the benefits of making the device as transparent as possible (see Denki, paragraph 0003).

Regarding claim 45 and 47, Wendler teaches that subcomponents of the catheter can be made by extrusion and injection molding (col. 4, lines 1-25; col. 7, lines 52-61).

Claims 28-32, 35-38, 40-43 and 46 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Wendler and Oda as applied to claims 24-27, 44, 45 and 47 above, and further in view of Stehr *et al.* (WO 96/29962 A1; hereinafter “Stehr”).

Wendler and Oda do not disclose a tip manufactured separately from the sheath.

Stehr teaches a condom catheter where the sheath and tip are manufactured separately (page 5, line 20-page 6, line 13).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to separately form the tip and sheath as shown by Stehr in the device and methods of Wendler and Oda in order to provide for a catheter with a tip with different physical properties (for example, breathability) than the sheath.

Regarding claims 28 and 32, Stehr teaches a breathable condom catheter (page 4, lines 13-17).

Regarding claim 29, the references do not disclose the claimed ranges of values for thickness and permeability.

Optimization of ranges within prior art conditions or through routine experimentation is not sufficient to patentably distinguish an invention over the prior art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

A particular parameter must first be recognized as a result-effective variable, i.e., a

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variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

One of ordinary skill in the art would have recognized the benefit of increasing the permeability as much as possible while keeping it liquid-tight. Thinner material lead to a more conformable product, while thicker materials have greater strength.

Regarding claims 30 and 31, Stehr teaches that the elastomer is a polyurethane (page 4, lines 13-17).

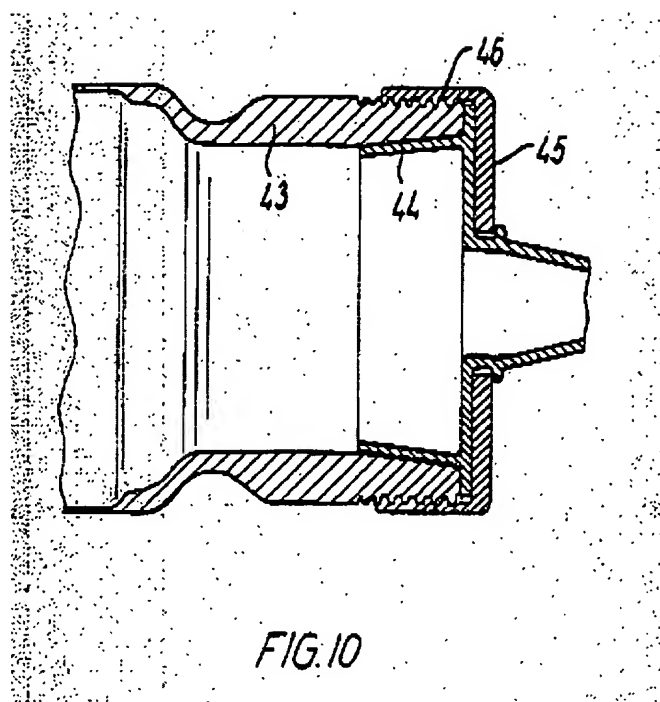
Regarding claims 35-37, Oda teaches the addition of a polymer (paragraph 0063).

Regarding claim 38, Oda teaches a polyethylene elastomer (paragraph 0058).

Regarding claims 40 and 41, Wendler teaches a pressure-sensing adhesive (7) and an adhesive rejecting/release layer (8).

Regarding claim 42, Wendler teaches a separate adhesive element (7).

Regarding claim 43, Wendler teaches interlocking elements (46)(see figure 10, *infra*).



Claims 33, 34 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wendler and Oda as applied to claims 24-27 and 44, 45 and 47 above, and further in view of Endo *et al.* (US 5,417,981 A; hereinafter: "Endo"), Hull *et al.*, (US 4,710,532; hereinafter "Hull") and Lee *et al.* (US 6,520,934 B1, hereinafter: "Lee").

Wendler and Oda do not teach the specifically claimed plasticizer and polymers.

Endo teaches catheters utilizing ethylene-polypropylene-diene terpolymer (col. 3, line 57- col. 4, line 4; claim 11).

Hull teaches catheters using citrate plasticizers (col. 1, lines 11-30).

Lee teaches catheters using polyamide-polyethylene block copolymer (col. 3, lines 45- 54).

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At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the plasticizers and polymers of Hull, Lee and Endo in the catheter of Wendler and Oda in order to provide materials known in the art to be suitable for that purpose.

Regarding the claimed % ranges of claims 34 and 39, optimization of ranges within prior art conditions or through routine experimentation is not sufficient to patentably distinguish an invention over the prior art. See *In re Aller*, supra.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MB

Michael Bogart

31 March 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

Tatyana